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APPLICATION NO.	[1	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
10/016,627		12/10/2001	Emil Wei-Ming Fu	4-31692A	4092
1095	7590	09/10/2004		EXAMINER	
NOVARTI		LIECTIAL DDODE	VENCI, DAVID J		
CORPORATE INTELLECTUAL PROPERTY ONE HEALTH PLAZA 430/2				ART UNIT	PAPER NUMBER
EAST HAN	OVER, 1	NJ 07936-1080	1641		
				DATE MAILED: 09/10/2004	

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)					
	10/016,627	FU ET AL.					
Office Action Summary	Examiner	Art Unit					
	David J Venci	1641					
The MAILING DATE of this communication app	<u>i</u>						
Period for Reply							
A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.1 after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a replication of the period for reply specified above, the maximum statutory period Failure to reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	36(a). In no event, however, may a reply be tim y within the statutory minimum of thirty (30) day will apply and will expire SIX (6) MONTHS from , cause the application to become ABANDONE	nely filed s will be considered timely. the mailing date of this communication. D (35 U.S.C. § 133).					
Status							
1) Responsive to communication(s) filed on 03/15	9/02.						
	action is non-final.	•					
closed in accordance with the practice under E	closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims							
4) Claim(s) <u>1-49</u> is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) is/are allowed. 6) Claim(s) <u>1-49</u> is/are rejected. 7) Claim(s) is/are objected to.							
8) Claim(s) are subject to restriction and/o	r election requirement.						
Application Papers							
9) The specification is objected to by the Examine 10) The drawing(s) filed on is/are: a) accomplicated any not request that any objection to the Replacement drawing sheet(s) including the correct 11) The oath or declaration is objected to by the Example 11.	epted or b) objected to by the Edrawing(s) be held in abeyance. See ion is required if the drawing(s) is obj	e 37 CFR 1.85(a). ected to. See 37 CFR 1.121(d).					
Priority under 35 U.S.C. § 119							
 12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of: 1. Certified copies of the priority documents 2. Certified copies of the priority documents 3. Copies of the certified copies of the priority documents * See the attached detailed Office action for a list 	s have been received. s have been received in Application rity documents have been receive u (PCT Rule 17.2(a)).	on No d in this National Stage					
Attachment(c)							
Attachment(s) 1) Notice of References Cited (PTO-892)	4) Interview Summary	(PTO-413)					
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date	Paper No(s)/Mail Da						

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DETAILED ACTION

Specification

The disclosure is objected to because of the following informalities:

On page 7, the paragraph beginning "Figure 2.", the sentence beginning "A 2-Da mass shift between (A) and (B)..." is indefinite because it is unclear how a mass shift is indicative of differential protein expression when the specification has not yet defined "differentially expressed."

On page 7, the paragraph beginning "Figure 3.", the sentence beginning "A 4-Da mass shift between (A) and (B)..." is indefinite because it is unclear how a mass shift is indicative of differential protein expression when the specification has not yet defined "differentially expressed."

The apparent interchangeable usage of the terms "inverse" (see e.g. p. 15, second paragraph, "the inverse should be observed..."), "reversal" (see e.g. p. 11, first paragraph, "an isotope peak intensity ratio reversal..."), "converse" (see e.g. p. 11, second paragraph, "two converse collaborative labeling experiments...") and "inverted" (see e.g. p. 19, "When the labeling is inverted...") is indefinite. Applicants are required to provide definitions for each of these terms, or provide correlation to art-recognized definitions.

Appropriate correction is required.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful

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process ... may obtain <u>a</u> patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer <u>cannot</u> overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-49 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-49 of copending Application No. 10/412,964. This is a <u>provisional</u> double patenting rejection since the conflicting claims have not in fact been patented.

Allowable Subject Matter

Claims 1-49 are allowable.

The following is a statement of reasons for the indication of allowable subject matter:

Applicants' claimed invention embodies, *inter alia*, a method for the spectrometric determination of differentially expressed proteins. Both the instant invention and the prior art teach a mass spectrometric method for the determination of differentially expressed proteins using isotopically labeled internal standards. For example, the prior art teaches a method comprising two protein mixtures — an experimental mixture and a reference mixture — where one or both of the mixtures are isotopically labeled. After labeling, the two mixtures are combined and analyzed by mass spectrometry. Intra-spectra analysis of labeling patterns

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is used to identify and quantify proteins in the experimental mixture (see e.g. Gygi et al. 17 NAT. BIOTECHNOL. 994 (1999).

The prior art does not appear to teach or suggest the specific step of providing four protein mixtures: an isotopically heavy-labeled reference pool, an isotopically heavy-labeled experimental pool, an isotopically light-labeled reference pool, and an isotopically light-labeled experimental pool (see claims 1(b), 23(b), 35(c), 47(a)). The prior art does not appear to teach or suggest the specific steps of combining the isotopically light-labeled reference pool with the isotopically heavy-labeled experimental pool (see claims 1(c), 23(c), 35(d), 47(b)), and combining the isotopically heavy-labeled reference pool with the isotopically light-labeled experimental pool (see claims 1(d), 23(d), 35(e), 47(c)). Finally, the prior art does not appear to teach or suggest the step of inter-spectra analysis or comparison of labeling patterns of the aforementioned combined pools to identify differentially expressed proteins (see claims 1(f), 23(f), 35(g), 47(e)).

Therefore, Applicants' method for identifying differentially expressed proteins appears to be free of the prior art.

Conclusion

Claims 1-49 are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J Venci whose telephone number is 571-272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David J Venci Examiner Art Unit 1641

djv

LONG V. LE SUPERVISORY PATENT EXAMINER TECHNOLOGY CENTER 1600

69/07/04